

EXHIBIT D

FILED
10-15-2018
Clerk of Circuit Court
Waukesha County
2018CV001334

STATE OF WISCONSIN

CIRCUIT COURT

WAUKESHA COUNTY

CASE NO.: 18CV1334

CASE CODE: 30704

ALTAPURE, LLC
6040 W. EXECUTIVE DR, # K
MEQUON, WI 53092

PLAINTIFF

V.

SURFACIDE, LLC
407 PILOT CT., #300
WAUKESHA, WI 53188

and

OneBeacon Insurance Group
605 Hwy 169 North, Suite 800
Plymouth, MN 55441

DEFENDANTS

FIRST AMENDED COMPLAINT

Plaintiff, Altapure, LLC by its attorney, Carl L. Ricciardi, as and for its claims against Defendant alleges and shows to the court as follows:

I. CLAIMS BASED ON WISCONSIN STATUTE SECTION 100.18(11) (b) 2

Jurisdiction arises under Section 100.18 of the Wisconsin Statutes and more particularly, Section 100.18 (11) (b) 2

1. Plaintiff, Altapure, LLC, a limited liability company, organized and existing under the laws of the State of Wisconsin maintaining offices at 6040 W. Executive Drive, #K, Mequon, WI 53092; plaintiff is in the business of designing, manufacturing, and selling, high level disinfection equipment for the elimination of pathogenic bio-burden (Super Bugs), including, but not limited

to MRSA, CRE, VRE, C. aureus and C. difficile, to medical and other facilities in the State of Wisconsin and elsewhere.

2. Defendant, Surfacide, LLC is a Limited Liability Company organized and existing under the laws of the State of Delaware, and has at all times material hereto, conducted substantial and not isolated business transactions, including advertising, in the State of Wisconsin and maintains offices at 407 Pilot Ct., #300, Waukesha, WI 53188. Said defendant is in the business of manufacturing and selling UV light products, including its Helios system, to medical facilities in the State of Wisconsin and elsewhere. Defendant is not currently directly regulated by any agency of the Federal Government or the State of Wisconsin regarding the efficacy of its products or its advertising claims.
3. Defendant, OneBeacon Insurance Group, is upon information and belief, a foreign insurance company, licensed to do business, and is in fact doing business, in the State of Wisconsin and elsewhere maintaining corporate offices at 605 Hwy 169 North, Suite 800, Plymouth, MN 55441. It is believed that said Defendant issued its certain policy of liability insurance to Defendant Surfacide, LLC which policy provides coverage for its advertising and marketing claims.
4. That upon information and belief, with the recent failure of the antibiotic Colistin, the last “go-to” antibiotic of choice, the Center for Disease Control (CDC) has proclaimed that the “end of the antibiotic era” has arrived and further opined, that in the future, individuals infected by hospital acquired Super Bugs will die because there are no longer any totally effective antibiotics available to cure these infections.
5. That upon information and belief, there is no federal or state standard as to what constitutes clean for hospitals located in the State of Wisconsin. There is a consensus in the medical literature that the hospital environment is a direct cause of nosocomial or hospital acquired infections. Upon information and belief, and at all times material hereto, Defendant knew or should have known that the typical consumer of its products is not scientifically knowledgeable as to the laws of physics of UV light to know that Defendant's claims are untrue, deceptive, misleading and in violation of Section 100.18 Wisconsin Statutes.
6. Further, upon information and belief, hundreds of thousands of infected patients die each year from hospital acquired infections because antibiotics are no longer effective; pathogens have mutated as part of their survival mechanism and have become resistant to current antibiotic treatment. It is believed that there are currently no replacement effective antibiotics in the world pharmaceutical pipeline at this time.
7. The peer reviewed medical literature has clearly established that hospitals and nursing homes are a known reservoir for pathogenic bio-burden capable of causing serious injury and death. The purpose of disinfecting or terminal cleaning patient treatment spaces is to eliminate the risk of the transmission of a pathogenic organism to another patient, hospital staff members or visitors. OSHA requires that employers provide a safe place of employment for its workers, which includes an environment that is free of pathogenic organisms.
8. The peer reviewed literature has demonstrated that prior to the availability of no-touch technologies such as hydrogen peroxide vapor and fogging with PAA (peroxyacetic acid), and UV light products, manual methods of cleaning patient treatment spaces left up to 50% of the surfaces untouched and therefore not properly disinfected. The purpose of these technologies is to eliminate the risk of a patient contracting a deadly pathogenic infection that is resistant to antibiotics.

9. That upon information and belief, prior to the end of the antibiotic era, many Super Bugs including CRE, VRE, Ebola and *C. aureus* carried mortality rates of thirty-five to fifty percent (35-50%), in other words 35-50% of patients contracting these infections would die despite antibiotic treatment.
10. That upon information and belief, the peer reviewed literature has shown that the UV light products are ineffective against the emerging pathogen *C. aureus* which carries a significant mortality rate. *C. aureus* is found in medical facilities. While claiming to be able to provide a “clean room” with use of the Helios System, Defendant Surfacide has neglected to inform the purchasers of its products that its technology cannot kill *C. aureus*. Further, upon information and belief, the CDC has recommended that hospitals use an EPA approved chemistry for killing *C. aureus*.
11. It is well established that infections caused by *C. difficile* are the most common hospital acquired infections in American hospitals, including those located in Wisconsin; further, patients who contract such an infection are more likely to have a second and third recurrence. It is reported that 44,500 thousand patients died in 2017 as a direct result of contracting a *C. difficile* infection and caused \$5.4 billion in healthcare expense. In severe cases, patients may have to have part of their intestines removed. A *C. difficile* infection increases the cost of a hospital stay both to the hospital, patient and in the case of Medicare and Medicaid, to the government. Following the first occurrence, the likely hood of second recurrence may be as high as 60%.
12. That upon information and belief, *C. difficile* is one of the most difficult pathogens to kill. The spores may remain viable for many months and as the spore ages, its outer wall thickens preventing UV light from killing the organism. The published literature clearly shows that UV light products cannot eliminate *C. difficile* spores in an entire room and cannot achieve a 6 log kill on all surfaces if the user follows the manufacturer's recommended procedure. Because a total kill in an entire space cannot be obtained, that space constitutes a hazard to the safety of patients and staff. Defendant Surfacide, LLC knew or should have known that its products would leave a viable pathogenic residue but intentionally neglected to so advise its customers of that fact.
13. The United States Environmental Protection Agency (EPA) is, upon information and belief, the only Agency of the United States Government that has promulgated a performance definition for the term “disinfection”. Disinfection and the process of disinfecting has specific scientific meaning and is a process relied on by experts in the food, pharmaceutical, and medical fields.
14. Ultraviolet light (UV) represents that portion of the spectrum of light from 100 to 400 nanometers while UV-C light is found between 100 nm to 280 nm, but it is most effective as a germicidal agent from 260-270 nm.
15. That upon information and belief, there is no other recognized performance definition published by the scientific community, the State of Wisconsin, or the Federal Government, specifically for UV light products. All chemical products claiming the ability to “disinfect” must meet or exceed the EPA's performance criteria. Plaintiff's high level disinfection products must satisfy the EPA's strict standard in order to claim disinfection. Further, upon information and belief, Plaintiff has suffered a pecuniary loss because it must meet the strict EPA performance definition for disinfection while Defendant Surfacide can make claims of being able to achieve disinfection without actually meeting any federal or state performance standard. In other words its claims are meaningless. In addition, because Defendant and the UV light industry as a whole are unregulated, they can make unsupported claims regarding the time it takes to achieve “disinfection”, a result that is unattainable, but far less than competing chemical based products. This time difference has been used by Defendant as a marketing strategy.

16. The EPA's hospital performance definition for disinfection is set forth in section OCSPP 810.2200 and requires a 100 percent kill of a 6 log challenge of both *Staphylococcus aureus* and *Pseudomonas aeruginosa* in less than 10 minutes. That upon information and belief, Defendant's products cannot meet this requirement when following its recommended practice.
17. The EPA's hospital performance definition for disinfection of *C. difficile* is set forth in section OCSPP 810.2100 (d)(2) & (g) and requires a minimum 6 log reduction; no growth is accepted. That upon information and belief, Defendant's products cannot meet this standard when following its own recommended procedures.
18. At all times material hereto, and specifically within the last three years, Defendant Surfacide, has advertised its Helio UV System on its website and published sales materials, which is available to Wisconsin consumers including hospitals and nursing homes. Upon information and belief, within the last three years, Defendant has otherwise marketed its UV Helio system in written advertising and marketing materials in the state of Wisconsin and elsewhere, all in direct violation of Section 100.18 Wisconsin Statutes. Defendant's claims of being able to "disinfect all exposed surfaces in an area" are false and made with willful intent to deceive the purchases of its products. That upon information and belief, Defendant Surfacide filed several patents with the United States Patent Office, claiming to be able to achieve sterilization, this assertion is false, without a basis in science and was made with willful intent to deceive the patent office.
19. Defendant Surfacide, on its web site, makes claims of being able to: "disinfect all areas of the hospital environment", "that no surface is left untouched" and the product will achieve "hard surface disinfection". These claims are untrue, deceptive and misleading and are otherwise in violation of Section 100.18 Wisconsin Statutes. Further, Defendant encourages consumers to "call for Premier Sterilization" all with the knowledge that its UV light products have not been shown to reach that level of kill of pathogenic bio-burden. Sterilization requires a 100 percent kill of all pathogens, no viable survivors can remain. In other United States patents granted to Surfacide, it asserts that organisms in the shadowed areas will not be effected.
20. That upon information and belief, Defendant Surfacide's claims of being able to disinfect or to achieve disinfection are meaningless and without substance because the use of the word "disinfect" as used by Defendant refers to no performance standard published by the Federal Government or the State of Wisconsin. Defendant is, upon information and belief, unable to meet the EPA's definitions for hospital disinfection of *C. difficile* or any other recognized published scientific performance standard.
21. Defendant Surfacide, has intentionally borrowed the term "disinfection" from the regulation of the chemical industry by the EPA, knowing that its products do not meet the performance criteria for disinfection that is applicable to chemical disinfectants. The performance criteria for disinfection and sporicidal claims is relied upon by professionals in industries such as, but not limited to, food, hospital, and pharmaceutical, to prevent injury and loss of life.
22. Defendant Surfacide's claim that its UV light touches all exposed surfaces is intentionally false and deceptive because those surfaces in the shadows are not impacted by UV light. Leading peer reviewed published studies show that shadowing occurs when UV light products are used in a hospital setting. Even those surfaces that are in the line of sight, but beyond the effective kill range of UV-C light, are not effectively treated. Despite acknowledging this fact in its filed patents with the United States Patent Office, Defendant Surfacide, continued to make false claims about its ability to achieve disinfection in an entire treated space. Such claims are willful and in disregard

for the health and safety of its intended customers and their patients.

23. That, upon information and belief, Defendant Surfacide's claim of being able to disinfect "all areas of the hospital environment" is unsupported by the peer reviewed scientific literature. When making this untrue and deceptive claim, Defendant knew or should have known that UV light is incapable of achieving disinfection and/or a sporicidal effect on surfaces such, behind doors, fabrics, patient privacy curtains, under a toilet seat, under a patient bed, inside table drawers, in the shadows of objects within the room, or on the underside of furniture or other objects. Defendant knew or should have known that leaving a viable pathogenic bio-burden can cause serious injury or death to patients, visitors and staff.
24. It is an accepted fact, as shown in the published medical literature, that a patient placed in a space that was previously occupied by a patient with an infection, whether it be caused by *C. difficile*, MRSA, CRE, VRE or other, has a significant statistical probability of contracting the same infection. In the "end of the antibiotic era" this risk is both unnecessary and substantial.
25. That at all times material hereto, Defendant Surfacide, knew or should have known that there is no national standard of clean for American Hospitals. Defendant knew or should have known that hospital administrators and those involved in cleaning medical facilities rely on the claims of companies offering solutions to the hospital acquired infection problem when making decisions on purchasing no- touch technology to eliminate the risk of patients and others contracting a hospital acquired infection. Defendant had superior knowledge regarding the deficiencies in its technology and had a responsibility to not violate section 100.18 Wisconsin Statutes with untrue and misleading advertising.
26. Defendant knew or should have known that when its products achieve a certain log reduction on a surface, in the direct line of sight and at a distance of less than four (4) feet, this result cannot be extrapolated to support a claim of being able to achieve the same result on surfaces beyond that distance.
27. That upon information and belief, Defendant Surfacide's claims of being able to disinfect an entire room in its recommended period of time are false, deceptive and misleading and in violation of Chapter 100.18 of the Wisconsin Statutes because there is no peer reviewed data showing that UV light products can achieve that result. It is well established, in the scientific literature, that the ability of UV light to achieve a log reduction of common pathogens decreases inversely proportional to the square of the distance from the light source. It is also well established in the published literature that those pathogens in the shadows and beyond three meters are not killed and remain viable to cause an infection.
28. Defendant Surfacide, knew or should have known that *Clostridium difficile* (*C. diff*) infections are the leading cause of infectious diarrhea acquired in the hospital and causes significant mortality and morbidity. This infection is associated with an estimated cost in excess of \$6 billion annually in the United States. Further, Defendant knew or should have known that UV light products are ineffective in adversely affecting the spores of *C. difficile* beyond four (4) feet when following its recommended treatment procedures.
29. That upon information and belief, despite having access to the plethora of available published literature regarding the seriousness of hospital acquired infections and experts in the field, Defendant Surfacide intentionally made and continues to make unfounded, untrue and deceptive claims regarding the ability of its UV light product to eliminate the risk of a patient acquiring an infection in a medical setting that medical science cannot cure.

30. It is believed that unless restrained and enjoined, Defendant Surfacide will continue to make false, misleading and deceptive performance claims in the State of Wisconsin and elsewhere. Plaintiff lacks an adequate remedy at law.
31. That as a direct result of Surfacide's violation of section 100.18, Plaintiff has suffered a substantial pecuniary loss in that it has had to meet the performance standards imposed by the EPA on all chemical based products which require more time to achieve disinfection whereas Defendant claims to achieve the same result in less time. This false, deceptive and misleading claim is used to gain a marketing edge in the hospital market because time to return a room to patient use is a critical factor. That upon information and belief, Surfacide markets its UV light product as being able to achieve "disinfection" in a substantially shorter period of time; this marketing strategy is based on an untrue, deceptive and misleading premise.
32. The term "disinfection" has been defined in several dictionaries as follows:
- a. The process of killing pathogenic organisms or rendering them inert. *Mosby's Medical Dictionary, 9th edition. © 2009, Elsevier.* (emphasis added)
 - b. Destruction of pathogenic microorganisms or their toxins or vectors by direct exposure to chemical or physical agents.
Medical Dictionary for the Health Professions and Nursing © Farlex 2012 (emphasis added)
 - c. To use chemical substances to kill bacteria and other infecting agents outside the body or on the skin. Such substances include hexachlorophene, benzalkonium, cetrimide, phenol, merthiolate and various alcohols.
Collins Dictionary of Medicine © Robert M. Youngson 2004, 2005 (emphasis added)
 - d. The use of a disinfectant to destroy, inactivate or remove microorganisms that are likely to cause infection, spoilage or other undesirable effects in an inanimate object. Disinfection does not normally involve sterilization. (emphasis added)
Collins Dictionary of Biology, 3rd ed. © W. G. Hale, V. A. Saunders, J. P. Margham 2005 (emphasis added)
33. Surfacide's advertising claims of being able to "disinfect all areas of the hospital environment", "that no surface is left untouched" and the product will "achieve hard surface disinfection", do not meet the requirement of the discretionary definitions cited above as applied by Defendant in its marketing materials.

II. 15 U.S.C 1125(a) Section 43(b) Lanham Act Claim: Jurisdiction

34. Plaintiff incorporates the allegations of paragraphs 1-33 above as if set forth in full.
35. Defendant Surfacide has willfully asserted false and misleading statements of fact as to its UV light products.
36. That upon information, Defendant's advertising claims, and patent claims are designed to be deceptive and to mislead the consumer and the United States Patent Office as to the effectiveness of its UV light products including its Helois system.

37. That upon information, this deception is material to a customer's decision to purchase the UV light products because the false claims make the them look to be efficacious and easy to use.
38. The products sold by Defendant Surficide, upon information and belief are sold in interstate commerce and in the State of Wisconsin.
39. Plaintiff Altapure, has been damaged by Defendant' s false and untrue claims in that it has lost sales of its AP-4 High Level Disinfection System.
40. Defendant, Surficide's advertising and marketing claims of being able to clean all surfaces in a hospital and more specifically hard surfaces are false and misleading and are unsupported in the scientific literature.
41. Defendant's claim of being able to deliver “disinfection” is ambiguous and fails to meet any standard of the State of Wisconsin or the Federal Government and more specifically that of the EPA.
42. In making claims of being able to “clean all surfaces in a treated space” Defendant knew that this claim was false and was unsupported by any testing it had done or done by anyone else.
43. Surficide knew or should have known that its technology cannot achieve the disinfection performance standard established by the EPA.
44. Defendant knew or should have known that its technology has never achieved a 6 log kill of C. difficile in an entire treated space in a hospital on all walls an floor following the methodology it presents to its customers or prospective customers.
45. That Defendant, Surficide has never advised its customers of the inadequacy in its Helois UV light product in that it cannot clean an entire space or all of the exposed surfaces in a space.
46. Defendant knew or should have known that its Helois system is incapable of achieving a complete kill of MRSA, VRE, CRE, C. difficile in an entire space to be treated. Further, Surficide knew or should have known that its products cannot achieve sterilization in a patient treatment space and despite having no scientific basis, Surficide made such claims in its various documents submitted to the United States Patent Office.
47. Plaintiff has suffered a monetary loss as a direct result of Surficide's false and unsupported advertising claims and that Plaintiff will continue to suffer such loss unless it is enjoined and restrained from making false, misleading and unsupportable claims in its advertising materials.

Wherefore, Plaintiff demands judgment as follows:

A. CLAIM FOR INJUNCTIVE RELIEF

1. That Defendant, Surficide be enjoined and restrained from making claims of “disinfection” unless and until it can show its compliance with a published governmental performance standard, one that is equivalent to that published by the EPA. That it be restrained from claiming the ability to “disinfect an entire room” until it can provide peer reviewed evidence of that achievement.
2. That Surficide be required to contact its customers, in writing and clearly advise them that its products

cannot deliver disinfection, that its UV light product cannot treat all surfaces in a hospital or treat an entire space effectively. That its products cannot achieve sterilization of a patient treatment space.

3. That Surfacide post the following at the top of its web site "Home Page" in bold print:

- (a) That the performance of UV light products are seriously diminished by distance, shadows, and the angle of the treated surface relative to the UV light source,. Surfacide's UV light products do not meet the United States Environmental Protection Agency's definition for Disinfection, Hospital Disinfection, or as a Sporocidal for *Clostridium difficile* (C. difficile), or any other published performance definition of disinfection published by the Federal or State Governments.
- (b) That its claims for rendering a treated room "clean" or "disinfected", and surfaces within the treated room are "disinfected" are retracted.
- (c) That its claims for rendering a treated room safe from *Clostridium difficile* (C. difficile) are retracted.

Plaintiff is not, however, seeking damages for its past monetary loss, it only wishes to restrain Defendant from violating Sect. 100.18 in the future

B. CLAIM FOR DECLARATORY JUDGEMENT

Plaintiff requests that the court declare Surfacide's claims of being able to disinfect all areas of the hospital environment", "that no surface is left untouched", that its products will achieve hard surface disinfection on all surfaces in a treatment space , that its UV light product can "disinfect" or achieve sterilization, untrue, deceptive and misleading and in violation of Sect.100. 18 Wisconsin Statutes.

Plaintiff further requests that it be awarded its attorney fees, costs and other expenses as the court deems fair and equitable.

PLAINTIFF REQUESTS A TRIAL BY A JURY OF SIX

Dated this 9th. day of October, 2018

(signed electronically)
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